

Attorney Docket No.: **KBI-0015**
Inventors: **Ranganathan, Natarajan**
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REMARKS

Claims 1-11 are pending in the instant application. Claims 1-11 have been rejected. Claims 1-3 and 7-11 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Priority

The Examiner suggests that Applicant has not complied with 35 U.S.C. 120 because the instant specification fails to identify the current status of the parent cases. Accordingly, Applicant has amended the specification to update the status of the priority documents.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 2, 3, and 7 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claim 2 is suggested as being indefinite because the term "S. thermophilus" should be spelled out. In addition, claim 3 is suggested to be vague and indefinite for reciting "such as" in line 4 and repeating the phrase "brown sugar". Claim 7 is suggested to lack sufficient antecedent basis for the term "at least one prebiotic ingredient". Applicant has made the appropriate amendments to claims 2, 3, and 7 and respectfully requests that this rejection be withdrawn.

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III. Rejection of Claims under 35 U.S.C. §102

Claims 1-3 and 6 have been rejected under 35 U.S.C. 102(b) as being anticipated by Halpin-Dohnalek et al. (U.S. Patent No. 5,902,578). The Examiner suggests that Halpin-Dohnalek et al. teach a nutritional composition comprising protein, fat, carbohydrates and the probiotic *Lactobacillus reuteri*, *L. acidophilus*, and *Bifidobacterium infantis*. It is suggested that this references teaches that the composition is useful for maintaining GI health, and teaches a method for restoring GI health by administering the composition. It is suggested that Halpin-Dohnalek et al. teach the composition further comprises minerals and vitamins as well as sucrose and that the compositions provides $10 \times 10^9 - 5 \times 10^9$ CFU of bacteria of *L. reuteri*. Applicant respectfully disagrees.

Halpin-Dohnalek et al. teach a composition with an undisclosed amount of protein. In contrast, the instant nutritional food or product contains a protein ingredient which is from about 5% to about 80% by weight of the total weight of the nutritional food or product (see page 19, lines 18-20, of the specification). Accordingly, in an earnest effort to clarify the instant invention, Applicant has amended claim 1 to recite that the nutritional food or nutritional product comprises about 5% to about 80% by weight of at least one protein ingredient. Because Halpin-Dohnalek et al. fail to teach or suggest such a composition, this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

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Claims 1, 3-6 and 8 have been rejected under 35 U.S.C. 102(b) as being anticipated by Jungvid (U.S. Patent No. 5,085,874). The Examiner suggests that Jungvid teaches nutritional compositions comprising vegetable proteins, whey, vitamins, sodium caseinate, fat (lard, soy oil), animal proteins, starch (a prebiotic), dextrose (carbohydrate), minerals, probiotics (*Lactobacillus bulgaricus*, which hydrolyzes nitrogenous waste products) and lactulose. Applicant respectfully disagrees.

Jungvid teaches that the fat content of the disclosed nutritional composition is 30-36% (see Examples 1-3 and claim 1). In contrast, the instant nutritional food or product is distinct in that the fat ingredient is from about 2% to about 12% by weight of the total weight of the nutritional food or product (see page 16, lines 24-26, of the specification). Accordingly, in an earnest effort to clarify the instant invention, Applicant has amended claims 1 and 8 to recite that the nutritional food or nutritional product comprises about 2% to about 12% by weight of at least one fat ingredient. Because Jungvid fails to teach or suggest such compositions, this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1, 3-5, 7 and 9-10 have been rejected under 35 U.S.C. 102(b) as being anticipated by Paul (U.S. Patent No. 5,744,134). The Examiner suggests that Paul teaches a composition for restoring and maintaining GI health comprising immunoglobulins (protein), FOS (prebiotic), pectin (prebiotic), *Lactobacillus* and *Bifidobacteria* (abstract). It is suggested that the immunoglobulin, or protein, is derived from milk or whey

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(abstract); and the *Lactobacillus* may be *L. acidophilis*, *bulgaricus*, *casei*, *fermentum*, *salivarois*, *brevis*, *plantarum*, *Bifidobacterium adolescentis*, *infantis*, *longum*, *thermophilus*, or *bifidum*. It is suggested that Paul further teaches that the composition comprises carbohydrates such as maltodextrin and lactose; lipids such as lecithin; and methods for restoring and maintaining GI health, comprising administering the composition. Applicant respectfully disagrees.

Paul teaches a formulation comprising 40% to 60% by weight of an immunoglobulins composition and 40% to 60% by weight of a soluble dietary fiber selected from the group consisting of inulin, fructo-oligosaccharides, pectin, guar gum, and mixtures thereof (paragraph bridging columns 3 and 4). Paul further teaches that the immunoglobulin composition may be composed of 55-60 parts by weight of an immunoglobulin concentrate from bovine whey, about 35-40 parts by weight of a mixture of carbohydrates including rice maltodextrin and lactose, and about 5-10 parts by weight of lipid. As such, the resulting carbohydrate content of the formulation is less than 24% by weight. In contrast, the carbohydrate content of the instant nutritional food or product is from about 47% to about 82% by weight (see page 16, lines 15-18, of the specification). Moreover, the prebiotic ingredient of the instant nutritional food or product is from of about 2% to about 6% by weight (see page 18, lines 16-18, of the specification). Further, the probiotic of the instant nutritional food or product provides about 5 billion to 20 billion colony forming units of bacteria (see page 18, lines 29-31). Accordingly, in an earnest effort to highlight these features of the instant invention, Applicant has

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amended claim 1 to recite that the nutritional food or nutritional product comprises about 47% to about 82% by weight of at least one carbohydrate ingredient, amended claim 9 to recite that the food or nutritional product comprises from about 2% to about 6% by weight of prebiotic, and amended claim 10 to indicate that the probiotic provides about 5 billion to 20 billion colony forming units of bacteria. Because Paul fails to teach or suggest such compositions, this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1, 3-5, 7 and 10-11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Costanzo et al. (U.S. Patent No. 5,518,740). The Examiner suggests that Costanzo et al. teach a yogurt composition (abstract) comprising *Lactobacillus bulgaricus* (probiotic), whole milk (milk proteins), dextrose (carbohydrate) and inulin (a prebiotic) (Example 1). It is further suggested that Costanzo et al. teach yogurts comprising *Lactobacillus bulgaricus*, whole milk, dextrose, banana smash (prebiotic, banana fiber), and soy lecithin (fat) (Example 2), wherein the compositions may further comprise pectin (prebiotic) (Example 3). Applicant respectfully disagrees.

The yogurt of Example 1 of Costanzo et al. comprises 57.75% nature whole yogurt containing living ferments, 19.25% whole milk containing living ferments, 14.77% dextrose, and 4.7% inulin. The yogurt of Example 2 of Costanzo et al. comprises 36.18% nature whole yogurt containing living ferments, 36.18% whole milk containing living ferments, 19.06% dextrose, 6.89% banana smash, and 0.02% soya lecithin. The yogurt of Example 3 comprises 41.8% apple smash, 15.0% natural whole yogurt, 8.0% dextrose, 0.5%

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pectin, and 33.0% apple slices. In contrast, the nutritional food or nutritional product of amended claim 1 comprises at least one probiotic bacteria, about 47% to about 82% by weight of at least one carbohydrate ingredient, about 2% to about 12% by weight of at least one fat ingredient, and about 5% to about 80% by weight of at least one protein ingredient. Further, as indicated above, the food or products of the instant invention provides about 5 billion to 20 billion colony forming units of bacteria in the probiotic ingredient. Thus, to highlight this feature, claim 11 have been amended to indicate that the probiotic provides about 5 billion to 20 billion colony forming units of bacteria. Because Costanzo et al. fail to teach or suggest the compositions set forth in claims 1, 3-5, 7 and 10-11, this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

IV. Double Patenting

Claim 10 has been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,706,287. Applicant has filed herewith a terminal disclaimer in compliance with 37 CFR 1.321(c) and therefore respectfully requests that this rejection be withdrawn.

V. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata
Registration No. 32,257

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515